

relationship can be shown to be distinct if either of the following can be shown: (1) that process as claimed can be practiced with another materially different product; or (2) that the product as claimed can be used in a materially different process. The Examiner goes on to state that, in the present application, the assay of Group III can be performed using a materially different product than that in Group I, namely horseradish peroxidase.

Applicant submits that the reason offered by the Examiner is insufficient to support a conclusion of patentable distinctness between the restricted claims. The Examiner has provided no indication as how horseradish peroxidase would accomplish the same results as the chelated complex comprised of a labeled antibiotic suggested in Group I. Moreover, the complex as claimed acts as a bacterial probe capable of detecting low cell numbers.

Accordingly, because the Office has not carried the burden of providing technologically sound reasons or examples for concluding that the claims of the restricted groups are patentably distinct, the restriction requirement between the claims of Group I and Group III is improper and should be withdrawn.

The Office has characterized the relationship between Groups II and I as process of making and product made. Citing MPEP §806.05(f), the Examiner states that claims in this relationship can be shown to be distinct if either of the following can be shown: (1) that the process as claimed can be used to make another and materially different product; or (2) that the product as claimed can be made by another and materially different process. The Examiner goes on to state that, in the present application, the method can be used to make a materially different product such as using nonglycopeptide with a different metal in solvent to form a different chelated antibiotic-metal complex. Applicant submits that the reason offered by the Examiner is insufficient to support a conclusion of patentable distinctness between the restricted claims. The Examiner has provided no indication as to the means or the feasibility of using the claimed method to make a different product. Furthermore, the Examiner does not address the utility in the alternative chelated antibiotic-metal complex or how it would perform differently than the claimed product.

Accordingly, because the Office has not carried the burden of providing technologically sound reasons or examples for concluding that the claims of Group II and

Group I are patentably distinct, the restriction requirement is improper and should be withdrawn.

The Office has characterized the relationship between Groups III and IV as process and apparatus for its practice. Citing MPEP §806.05(e), the Examiner states that claims in this relationship can be shown to be distinct if either of the following can be shown: (1) that the process as claimed can be practiced by another, materially different apparatus or by hand; or (2) that the apparatus as claimed can be used to practice another and materially different process. The Examiner goes on to state that, in the present application, the process can be practiced by another and materially different apparatus such as commercially available western detection kits. Applicant submits that the reason offered by the Examiner is insufficient to support a conclusion of patentable distinctness between the restricted claims. The Examiner has provided no indication as to how performing the process by another apparatus is materially different from using the claimed method to perform the process.

Moreover, as claimed, Claim 34 explicitly recites a kit "for conducting a chemiluminescent assay of microorganisms..." using language that mirrors the process claims. In short, the kit as claimed is specifically designed to carry out the process of Group III. As the Examiner suggests, a western detection kit primarily is used for assaying protein. If the kit in Group IV were used otherwise, it would not be the same kit as claimed.

Accordingly, because the Office has not carried the burden of providing technologically sound reasons or examples for concluding that the claims of the restricted groups are patentably distinct, the restriction requirement between Group III and Group IV is improper and should be withdrawn.

The Office has characterized the relationship between Groups I and IV, Groups II and IV, and Groups II and III, as being unrelated. In each instance, the Office cites to MPEP § 802.01 and §806.06, noting that claims in this relationship can be shown to be distinct if the claimed inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

The Examiner discusses only the relationship between Group I and Group IV. With respect to Groups I and IV, the Office states that complex of Group I and the kit of Group IV are not disclosed as capable of use together and, more generically, unrelated.

Applicants respectfully traverse each of these restrictions. For claims to be found unrelated, the Office must show **both** that the claims are not disclosed as capable of use together **and** they have different modes of operation, different functions, or different effects. Applicants traverse each of these restriction requirements because the Office has not shown how its stated examples amount to different modes of operation, different functions, or different effects; nor has the Office articulated how the claims are incapable of use together. Consequently, because the Office has not carried its burden to establish that the groups of claims as identified by the Examiner are unrelated, Applicants submit that the restrictions between Groups I and IV, Groups II and IV, and Groups II and III are all improper. Withdrawal of these restriction requirements are now respectfully requested.

Applicants traverse the election of species requirement. In the same fashion as a restriction requirement, an election of species requirement is proper only if the restricted species are independent or patentably distinct **and** there is no serious burden placed on the Office if an election is not required (MPEP §803). The burden is on the Office to provide reasons and/or examples to support any conclusion of patentable distinctness between the restricted species (MPEP §803). Applicant respectfully traverses the restriction requirement on the grounds that the Office has not carried the burden of providing any reason and/or example to support the conclusion that the restricted species are, in fact, distinct, and that there is no burden on the Office if the election of species is not required.

With regard to election of species requirements involving Markush-type claims, the Examiner's attention is directed to MPEP §803.02:

*If the members of the Markush groups are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner **must** examine all claims on the merits, even though they may be directed to independent and distinct inventions. In such a case the, examiner will not follow the procedure described below and **will not** require provisional election of a single species.*

In the present case, Applicants respectfully note that the Markush recitation of Claims 1 and 12 recites only three classes of antibiotics: glycopeptide antibiotics, ribonucleoside antibiotics, and quinolone antibiotics. Three members is an exceedingly small and well-contained group. While each of the classes includes multiple examples, all of the members of each class perform in similar manners and are thus very closely related.

In the present case, Applicants respectfully note that the Markush recitation of Claims 1 and 12 recites only two classes of metals: transition metals and lanthanide metals. Two types of metals is an exceedingly small and well-contained group. While each of the types includes multiple examples, all of the members of each type perform in similar manners and are thus very closely related.

In the present case, Applicants respectfully note that the Markush recitation of Claims 11 and 29 recites only four classes of microorganisms: gram-positive bacteria, Mycobacteria, permeabilized gram-negative bacteria, and protozoans. Four classes is an exceedingly small and well-contained group. While each of the classes includes multiple examples, all of the members of each class perform in similar manners and are thus very closely related.

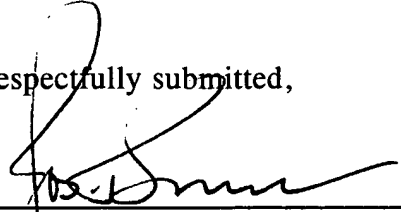
Therefore, Applicants submit that there is no serious burden on the Office if the election of species is not made. Therefore the Office "must" Examine the entire Markush group on the merits as per MPEP §803.02. Applicants note that with the provisional election of a single species, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claims will be extended (MPEP §803.02). Therefore, Applicants respectfully submit that the election of species requirement is improper. Withdrawal of the election of species requirement is respectfully requested.

Applicants explicitly reserve their right to rejoin suitable method claims upon an indication of allowable product claims. See *In re Ochiai*, 37 USPQ2d 1127, and *In re Brouwer*, 37 USPQ2d 1663.

CONCLUSION

Applicants submit that the application is now ready for examination on the merits.
Early notification of such action is earnestly solicited.

Respectfully submitted,



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